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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/091,742	03/05/2002	James H. Anderson	56,492 (71699)	8190

21874 7590 02/12/2008

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EXAMINER	
PINHEIRO, JASON PAUL	
ART UNIT	PAPER NUMBER
3714	
MAIL DATE	DELIVERY MODE
02/12/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/091,742	ANDERSON ET AL.	
	Examiner	Art Unit	
	Jason Pinheiro	3714	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *10/17/2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-37,44,46-63 and 74-89* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-37, 44, 46-63 and 74-89* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 10/17/2007 has been entered.

Response to Amendment

2. After the amendment filed on 10/17/2007, Claims 1, 3, 6, 7, 16, 44, 52, 74-75 and 84 were amended. As a result claims 1-37, 44, 46-63 and 74-89 are pending.

Claim Rejections - 35 USC § 102

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

4. Claims 1-2, 6, 9-10, 52 and 75-76 are rejected under 35 U.S.C. 102(e) as being anticipated by Alexander et al. (US 2004/0076940).

Regarding claims 1 and 75-76: Alexander '940 discloses a simulator system comprising a manikin including a simulated body cavity or lumen and an interface device (paragraph [0045] – paragraph [0046]) (Fig. 1); a medical device having a first end for manipulation by a first user and a portion having a second end that is insert-able into the simulated body cavity or body lumen (paragraph [0045] – paragraph [0046]), wherein the simulator system simulates the use and movement of the medical device in the simulated body cavity or lumen of the manikin (Abstract); that the interface device is configured to receive the medical device portion having the second end and also to interface with the simulated body cavity or lumen (paragraph [0048]); that the interface device includes an active directional force feedback mechanism, the active directional force feedback mechanism being configured so as to exert directional force directly on the medical portion in response to a feedback signal received by the force

feedback mechanism (paragraph [0053]); a computational engine embodying physically based modeling using finite element methodology, the computational engine simulating interactions between the medical device and body cavity or lumen, the interactions relating to the manipulation of the medical device by the first user (paragraph [0046]); and that the computational engine models interactions between the medical device and the body cavity or lumen in three dimensions, computes forces that would arise from interactions between the medical device and body cavity or lumen and outputs feedback signals corresponding to the computer forces to the active directional force feedback mechanism so as to thereby feedback said computed forces to the user (paragraph [0013]); and at least one first display device being operably coupled to the processor engine and for displaying a three dimensional representation of the simulated body cavity or lumen and a three dimensional representation of the medical device within the simulated body cavity or lumen (paragraph [0046], paragraph [0058], Fig. 2).

Regarding claim 2 and 52: Alexander discloses that the active directional force feedback system is configured so as to provide resistance to forward motion but enable free reverse motion in response to the feedback signal (paragraph [0088]).

Regarding claim 6: Alexander discloses that a tactile feedback mechanism that is selectively coupled to the medical device so as to simulate forces being exerted on the medical device, these simulated forces being different from the

directional forces associated with the interactions between the medical device and the body cavity or lumen (paragraph [0046]).

Regarding claim 9: Alexander discloses a user display and a tracking device for continuously tracking a position of at least the medical device second end relative to the simulated body cavity or lumen within the manikin, wherein the user display displays the simulated body cavity or lumen and the medical device based on its relative position and movement (paragraph [0007], paragraph [0070])

Regarding claim 10: Alexander discloses an encoder for tracking the translation of the device and an encoder for tracking the rotation of the device, the translation and rotational encoders being embodied in the medical device (paragraph [0022]).

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

6. Claims 3-5. 11, 16-23, 25, 28, 30, 33-35, 37, 47-48, 53-55, 57-58, and 61-62 are rejected under 35 U.S.C. 103(a) as being unpatentable over Alexander et al. (US 2004/0076940) in view of Chosack et al. (WO 9938141).

Regarding claims 3-5: Alexander discloses that which is discussed above. However Alexander does not disclose that the active directional force feedback mechanism includes a rolling element coupled to the medical device portion having the second end and wherein an internal surface of the simulated cavity or lumen in the manikin includes an oblique slot and wherein the active directional force feedback mechanism is arranged so that the rolling element is receivable in the oblique spot; that in response to a feedback signal, forward movement of the medical device second end causes the rolling element to be received by the slot thereby causing resistance to forward motion; or that the active directional force feedback mechanism includes a motor, where the motor controls movement of the rolling element.

Chosack '141 does disclose that the active directional force feedback mechanism includes a rolling element coupled to the medical device portion having the second end and wherein an internal surface of the simulated cavity or

lumen in the manikin includes an oblique slot and wherein the active directional force feedback mechanism is arranged so that the rolling element is receivable in the oblique spot (*fig. 7(a)-(d); p. 24, 16 - p. 25, 2*); in response to a feedback signal, forward movement of the medical device second end causes the rolling element to be received by the slot thereby causing resistance to forward motion (*fig. 7(a)-(d); p. 24, 16 - p. 25, 2*); and that the active directional force feedback mechanism includes a motor, where the motor controls movement of the rolling element (*p. 25, 13-21*).

Therefore it would have been obvious to one skilled in the art at the time the invention was made to integrate the teachings of Chosack into the teachings of Alexander in order to yield the predictable result of creating a mannequin, which is used for medical simulation, that more closely emulates the reaction a human would have during certain procedures.

Regarding claim 11: Chosack discloses an optical tracking unit embodied in the manikin, the optical tracking unit including a light source, a signal processing circuit and one or more optical sensors, wherein the optical tracking unit is placed within the interface device so as to be in optical communication with the device when it is inserted in the simulated cavity or lumen (*fig. 9(a)-(d); p. 28, 18 – p. 29, 2; More specifically, when the device is inserted in the manikin, various tools can be inserted into the device, wherein the tools are tracked with optical sensors.*).

Regarding claim 16: Chosack discloses that one or more additional medical devices are inserted into the interface device wherein each of said one or more additional medical devices includes a first end for manipulation by a user and a portion including a second end for insertion into the simulated body cavity or body lumen, the position relative to the simulated body cavity or lumen of each of the one or more additional medical device inserted into the interface device is independently tracked, and the display displays the relative position and movement of each of the one or more additional medical devices and the simulated body cavity or lumen (*fig. 9(a)-(e); p. 28, 18 - p. 29, 2*).

Regarding claims 17, 37 and 61: Chosack discloses various medical devices including endoscopes, forceps and coils (*fig. 9(a)-(e); p. 28, 1- p. 29, 2*). The remaining devices are admitted equivalents.

Regarding claim 18: Chosack discloses a table for placing the manikin thereon, wherein the table comprises a processor connectable to a network (*fig. 1, 3B(80)*).

Regarding claim 19: Chosack discloses at least one first user device being operably coupled to the computational engine, wherein the first user device includes a first display device that displays a three-dimensional representation of the simulated body cavity or lumen of a patient (*fig. 1, 3B(80)*).

Regarding claim 20: Chosack discloses that the first display device further displays a three dimensional representation of the medical device along with the simulated body cavity or lumen and wherein the computational engine simulates

the movement of the medical device within the simulated body cavity of the manikin in real-time as a first user manipulates the medical device in the simulated body cavity or lumen within and causes such simulations to be displayed on the first display device (*fig. 2-3(a); p. 12, 5-14; p. 7, 19-25; p. 10, 23-29*).

Regarding claim 21: Chosack discloses a simulated scanning display that displays an image that is representative of one of a two-dimensional scanned image or a three-dimensional reconstructed scanned image of the simulated body cavity or lumen (*p. 7, 4-15*).

Regarding claim 22: Chosack discloses a simulated scanning device and wherein the simulated scanning display is part of the simulated scanning device (*p. 7, 16-18; p. 14, 8-20*).

Regarding claim 23: Chosack discloses that the simulated scanning device is simulating one of an x-ray imaging system, an MRI imaging system or an ultrasonic imaging system (*p. 7, 16-18; p. 14, 8-20*).

Regarding claim 25: Chosack discloses a re-configurable control panel for performing image acquisition selection and image display (*fig. 2, 3B(42); p. 12, 5-32*).

Regarding claim 28: Chosack discloses the computational engine is operably coupled to a database of patient images and/or medical data so the patient images and/or medical data can be obtained and displayed to the first user (*fig. 2, 3B(42); p. 12, 5-32*).

Regarding claim 30: Chosack discloses the patient images comprise images of a body cavity or lumen from a patient affected by a pathology (*fig. 2, 3B(42); p. 12, 5-32*).

Regarding claim 33: Chosack discloses that the first user device is configured so as to allow the first user to access the database of patient images and/or medical data, and wherein, in response to said accessing, the requested image and/or medical data is displayed on the first user display device (*fig. 2, 3B(42); p. 12, 5-32*).

Regarding claim 34: Chosack discloses the second display interface is configured so as to allow the second user to access the database of patient images and/or medical data, and wherein in response to said accessing, the requested image and/or medical data is displayed on the second display interface (*fig. 2, 3B(42); p. 12, 5-32*).

Regarding claim 35: Chosack discloses a monitoring station that includes a second user device and a second display interface to enable a second user to monitor the movement of the medical device within the simulated body cavity or lumen and wherein the second display interface is configured so as to allow the second user to access the database of patient images and/or medical data, and wherein, in response to said accessing, the requested image and/or medical data are displayed on the second display interface (*fig. 2, 3B(42); p. 12, 5-32*).

Regarding claim 47: Chosack discloses that the computational engine simulates deformation of the simulated body cavity or lumen by the medical device (*p. 13, 6-13; p. 16, 2-19*).

Regarding claim 48: Chosack discloses a computational engine simulating an operation of a medical device for a variety of procedures including surgical procedures (*p. 28,1-7; p. 29, 19-27*).

Regarding claim 53: Chosack discloses a processor in communication with the active directional force-feedback mechanism; and a first user device in operably coupled to the processor, the first user device comprising a first display interface for displaying a representation of a body cavity; and for providing access to a database of three-dimensional images of body cavities and lumens from a plurality of different patients; and enabling the first user to select from the database a representation, wherein in response to the selection, the representation is displayed on the first display interface (*fig. 1, 2, 3A, 3B, 5A, 5B, 9; p. 9, 29 - p. 11, 5; p. 11, 26 - p. 19, 20*)

Regarding claim 55: Chosack discloses a monitoring station that includes a second display interface in communication with the processor and the first display interface and wherein the second display interface provides a second user with access to the database (*p. 19, 12-20, 12*).

Regarding claim 57: Chosack discloses simulating the deformation of a body cavity or lumen in response to manipulation of the medical device in the

simulated body cavity or lumen by the first user and displaying the representation of the deformation on the first display interface (*p. 16, 2-31*).

Regarding claim 58: Chosack discloses performing an operation on the simulated body cavity or lumen using the medical device and displaying a simulation of the operation on the first display interface (*fig. 2*).

Regarding claim 62: Chosack discloses providing one or more additional medical devices, inserting the provided one or more additional medical devices into the simulated body cavity or lumen, and independently monitoring and displaying the movement of each inserted medical device (*fig. 9A-9E; p. 28,1 - p. 29:2*).

7. Claims 12-15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Alexander et al. (US 2004/0076940) in view of Chosack et al. (WO 9938141) as applied to claim 11 above, and further in view of Belson et al. (US 6610007)

Regarding claim 12**:** Alexander and Chosack disclose that which is discussed above. However neither Alexander nor Chosack disclose light from a light source reflecting on the device when inserted and wherein the reflected light is received by one or more optical sensors.

Belson discloses a method for tracking endoscopes whereby the scope's position is detected by reflecting on the device and having the reflected light is received by one or more optical sensors (*col. 13, 3-21*). Hence it is known to track the position of endoscopes by detecting light reflect off the device.

Therefore it would have been obvious to one skilled in the art at the time of the invention, in view of Belson, to modify the combined invention of Alexander and Chosack, wherein the linear position of a device is tracked inside a manikin's body, to add the feature of tracking the device by describe light from a light source reflecting on the device when inserted and wherein the reflected light is received by one or more optical sensors because the method is equivalent known in the art for the same purpose of tracking linear position.

Regarding claim 13: Chosack additionally discloses simulating the movement of the device in real-time on the user display in response to detection of movement by position sensors (*pp. 6:15-17; p. 7, 2*).

Regarding claim 14: Chosack describes tracking the Cartesian position (x, y, z) of the device (*p. 21, 18-31*). However Alexander, Chosack nor Belson expressly describe placing position sensors perpendicular to one another. Because position sensors typically sense one direction of movement, it is notoriously well known to position the sensors perpendicularly to allow them to sense position along each Cartesian axis. For example, common a computer mouse places optical encoders in perpendicular positions to tack the two-dimensional (x, y) position of the device. Hence, by official notice, in the system suggested by the combination of Alexander, Chosack and Belson, wherein the Cartesian position is tracked by reflected light sensors, it would have been obvious to an artisan at the time of the invention to place the placing position

sensors perpendicular to one another to capture to Cartesian position of the device.

Regarding claim 15: Belson additionally describes a tracking unit configured as a rail along which the device can move (*fig. 3-5*).

8. Claims 49 and 77-87 are rejected under 35 U.S.C. 103(a) as being unpatentable over Alexander et al. (US 2004/0076940) in view of Chosack et al. (WO 9938141) and further in view of Cai et al., *Parametrical Modeling Based on Multi-Layered Approach for Design and Validation of Catheterization Devices*, Proceedings of the IASTED Intl. Conf., Computer Graphics and Imaging, (hereinafter "Cai").

Regarding claims 49 and 77-86: Alexander and Chosack disclose applicant's basic inventive concept of a simulator system, substantially as claimed, but do not expressly disclose the simulated body cavity or lumen is a simulated blood vessel of a vascular system. Cai shows this feature to be old in the medical simulator art. Cai discloses that the simulated body cavity or lumen is a simulated blood vessel of a vascular system (*p. 33*); and the system models interactions, using said one of the computational engine or the processor, between the medical device and a wall of the blood vessel and computes forces that would arise from the interactions between the device and the vessel wall and feeds back signals to the interface device so as to thereby feed back such computed forces back to the first user (*p. 34*). Cai discloses all the remaining features of the claims 77-86 as described in the previous office action dated 10/27/2004, and, incorporated by reference herein. Cai teaches such surgical

procedures are becoming increasingly popular (*Abstract, 1-3*). Chosack teaches it is desirable use simulation devices to provide realistic medical training without endangering human patients (*p. 1, 27-30*). It would be beneficial for the combined simulator of Alexander and Chosack to allow for the possibility of using a simulated blood vessel as taught by Cai in order to provide realistic medical training for other increasing popular surgical procedures. This would increase the flexibility and usefulness of the product. Therefore, it would have been obvious to one of ordinary skill in the art at the time of the applicant's invention from the teaching of Cai to modify the combined simulator of Alexander and Chosack by including the simulated blood vessel as taught by Cai to increase the flexibility and usefulness of the simulator.

Regarding claim 87**:** Chosack discloses various medical devices including endoscopes, forceps and coils (*fig. 9(a)-(e); p. 28, 1- p. 29, 2*). The remaining devices are admitted equivalents.

9. Claims 7, 8, 63, 74, 88 and 89 are rejected under 35 U.S.C. 103(a) as being unpatentable over Alexander et al. (US 2004/0076940) in view of Chosack et al. (WO 9938141) and further in view of Rosenberg et al. (US 5,959,613).

Regarding claims 7, 63, 74, 88 and 89: The combined simulator as suggested by Alexander and Chosack does not describe the feature of providing continuous vibrational feedback to a user holding the device. Rosenberg discloses an analogous system which for simulating medical devices such as endoscopes (*col. 5, 18-27; col. 11, 18-34*). The system provides continuous

vibrational feedback to the user (*col. 14, 30-64*). In view of Rosenberg, it would have been obvious to an artisan at the time of the invention to modify the combined simulator suggested by Alexander and Chosack, wherein the system simulates vibration of tissues, to add the feature of continuous vibration feedback to a user holding a device. As suggested by Rosenberg the modification would enhance the simulator by providing accurate and realistic tactile sensations to the user (*col. 4, 3-26*). In addition, as suggested by Chosack, the providing more realistic medical training which replicates the tactile and visual sensations experienced during a procedure provides improved medical training (*p. 1, 27-30; p. 2, 29 - p. 3, 6*).

Regarding claim 8: The combined simulator suggested by Alexander and Chosack describes a medical device wherein a unit on the device's second end provides tactile feedback. Rosenberg describes providing vibration with a continuously rotating motor (*col. 9, 53-64*). Hence, when the combination is taken as a whole, it suggests to an artisan at the time of the invention medical device simulator with a continuously rotating motor its second end providing vibrational feedback to increase the realism of the system.

10. Claims 24 and 32 are rejected under 35 U.S.C. 103(a) as being unpatentable over Alexander et al. (US 2004/0076940) in view of Chosack et al. (WO 9938141) and further in view of Simon et al. (US 6,470,207) and Saunders (US 6,572,376).

Regarding claim 24: The simulator suggested by Chosack does not describe a movable C-arm of an x-ray imaging system for a scanning device within scanning distance of the manikin. Simon discloses methods for performing endoscopic surgery wherein scanner is coupled to a C-arm within scanning distance of a patient. It is known in simulation system to increase the realism of the system by simulating actual devices and thereby provide more effective training (*e.g., Saunders, col. 1, 47-52; col. 2, 8-16*). Hence, in view of Simon and Saunders, it would have been obvious to an artisan at the time of the invention to modify the simulator suggested by Chosack, wherein a scanning device is simulated, to add the feature of a movable C-arm of an x-ray imaging system for a scanning device within scanning distance of the manikin and thereby increase the realism and effectiveness of training.

Regarding claim 32: Simon describes using a foot pedal to activate the scanning device (*col. 11:44-64*).

11. Claims 26-27, 29, 31 and 56 are rejected under 35 U.S.C. 103(a) as being unpatentable over Alexander et al. (US 2004/0076940) in view of Chosack et al. (WO 9938141) and further in view of Pollak et al. (US 6,106,297) and Issenberg et al. "Simulation Technology for Health Care Professional Skills Training and Assessment", JAMA, Vol. 282, No. 9, p. 2.

Regarding claim 26: The combined simulator suggested by Alexander and Chosack does not describe a second user interface device connectable to the network and comprising a second display interface for enabling a second user to monitor to movement of the medical device. It is generally known in the field of simulation devices to provide interfaces allowing instructors and observers to monitor training (*e.g. Pollak, col. 1, 17-24*). Pollak discloses an analogous training simulator having a monitoring station comprising a second user interface device connectable to the network and comprising a second display interface for enabling a second user to monitor to movement of the device in a simulated scenario (*fig. 2, 7, 8; col. 1, 56 - col. 3, 58*). One of ordinary skill in the art considers techniques from training simulations in other fields in medical training (*Issenberg et al.*). Hence, it would have been obvious to an artisan at the time of the invention to modify the simulator suggested by Chosack, wherein a simulator is used for training users to operate a medical device within the simulated body cavity, to add the feature of a monitoring station comprising a second user interface device connectable to the network and comprising a second display interface for enabling a second user to monitor to movement of the medical

device. As described by Pollak, the modification would enhance the device by giving an instructor a consistent and easy-to-use graphical interface to control and monitor a training scenario (*col. 2, 43 – col. 3, 4*).

Regarding claims 27 and 56: Pollak additionally teaches a second display interface displaying selectable options enabling a second user to select or change parameters of the simulator and wherein the selection causes the three dimensional image of the simulated environment displayed to a first user to change or reflect the changed parameters (*col. 3, 9-13; col. 5, 44-59*). Hence, when the prior art is taken as a whole, the combination of Alexander and Chosack with Pollak, wherein the movement of a medical device inside a body cavity is simulated using a manikin, it suggests a second display interface displaying selectable options enabling a second user to select or change anatomical or physiological parameters of the simulated body cavity and wherein the selection causes the three dimensional image of the simulated body cavity displayed to a first user to change or reflect the changed parameters.

Regarding claim 29: Chosack discloses the system is connectable to a database of patient images or medical data so the patient images and/or medical data can be obtained and displayed to the first user (*fig. 2(42); col. 12, 5-36*).

Regarding claim 31: Chosack discloses the patient images comprise images of a body cavity or lumen from a patient affected by a pathology (*fig. 2, 3B(42); p. 12, 5-32*).

12. Claim 36 is rejected under 35 U.S.C. 103(a) as being unpatentable over Alexander, Chosack, Pollak and Issenberg, as applied to claim 26 above, in further view of Hon (US 6,074,213).

Regarding claim 36: The medical trainer suggested by Alexander, Chosack, Pollak and Issenberg describes all the features of the claim except enabling the first user display to display the information on the second user display. It is well known in training devices to allow users at different stations to selectively view the same image so that the users, instructors or observers interact on a common perspective. For example, Hon discloses an analogous training system, which enables a first user display to display, the information on the second user display (*fig. 9, 14, 17*). It would have been obvious to an artisan at the time of the invention to modify the medical training simulator suggested by Alexander, Chosack, Pollak and Issenberg, wherein an instructor/operator monitors the simulation from a second display station, to add the feature of enabling the first user display to display the information on the second user display to allow users at different stations to selectively view the same image so that the users, instructors or observers share a common perspective.

13. Claims 44, 46, 50-51 and 59-60 are rejected under 35 U.S.C. 103(a) as being unpatentable over Alexander et al. (US 2004/0076940) in view of Chosack et al. (WO 9938141) and further view of Merril (US 6,106,301).

Regarding claim 44: Alexander and Chosack disclose applicant's basic inventive concept of a system for simulating the movement of a medical device in the body cavity of a patient, substantially as claimed, but does not expressly disclose that the medical device comprises a syringe that simulates fluid delivery the syringe. Merril shows this feature to be old in the medical simulation art. Merril discloses a pushing element for pushing the fluid through the opening (*6; catheter*); a friction-producing element in communication with the pushing element (*col. 13, 54-57; Arm (34) applies force to catheter (6).*); and a motor in communication with the friction-producing element (*32; servomotor*) and comprising a signal-receiving element (*44; processor*), wherein the friction-producing element causes friction between the pushing element and a surface of the lumen of the housing upon activation by the motor in response to a signal received by the signal-receiving element (*col. 13, 54-57*), and further wherein the opening of the syringe (*Fig. 2 (18)*) is connectable to a connecting piece having a first end for receiving fluid from the opening and a second end for delivering fluid (*Fig. 2 (24); hose*). Merril teaches that this enhances the realism of a medical procedure simulation system (*col. 5, 50-57*). It would benefit the catheter simulation of Chosack to include the simulation of angioplasty as taught by Merril, using the simulated body cavity or lumen of Chosack, to enhance the

realism of the simulation. Therefore, it would have been obvious to one of ordinary skill in the art at the time of the applicant's invention from the teaching of Merril to modify the simulation of Chosack by including the angioplasty simulation of Merril to enhance the realism of the simulation.

Regarding claims 46 and 59: The simulator suggested by Chosack discloses all the features of the claim except simulating the deployment of a balloon within the body cavity comprising a delivery mechanism for controlling delivery of fluid through the balloon-inflating device to the balloon; a pressure sensor for monitoring pressure of a fluid delivered to the balloon by the balloon-inflating device and an electrical pressure meter for reading pressure determined by the pressure sensor, the electrical pressure meter being connectable to a processor and for transmitting a signal corresponding to a pressure value to the processor. Merril discloses an analogous system for simulating minimally invasive procedures wherein the device simulates deployment of a balloon within the body cavity comprising a delivery mechanism for controlling delivery of fluid through the balloon-inflating device to the balloon; a pressure sensor for monitoring pressure of a fluid delivered to the balloon by the balloon-inflating device and an electrical pressure meter for reading pressure determined by the pressure sensor, the electrical pressure meter being connectable to a processor and for transmitting a signal corresponding to a pressure value to the processor (*fig. 2; col. 7, 1-11; col. 16, 11-41*). In view of Merril, it would have been obvious to an artisan at the time of the invention to modify the simulator suggested by

Chosack to add the features of simulating deployment of a balloon within the body cavity comprising a delivery mechanism for controlling delivery of fluid through the balloon-inflating device to the balloon; a pressure sensor for monitoring pressure of a fluid delivered to the balloon by the balloon-inflating device and an electrical pressure meter for reading pressure determined by the pressure sensor, the electrical pressure meter being connectable to a processor and for transmitting a signal corresponding to a pressure value to the processor. As described by Merril, the modification would allow training in angioplasty and stent deployment procedures (*fig. 2; col. 7, 1-11; col. 16, 11-41*).

Regarding claims 50 and 51: Merril discloses simulating a minimally invasive procedure in blood vessels (*col. 8, 17-29*). It is within the implicit knowledge of an artisan that minimally invasive procedures are performed in the blood vessels of the brain and heart. Hence, it would have been obvious to an artisan at the time of the invention to modify the medical device simulate discloses by Chosack, wherein the device simulates a minimally invasive medical procedure, to add the feature of simulate the movement of devices through blood vessels in the brain and heart. As suggested by Chosack the modification would enhance the device by allowing users to gain skills necessary to perform procedures without requiring practice (*col. 5, 50-57*).

Regarding claim 60: Merril discloses the operation being the injection of a radio-opaque fluid within the body cavity or lumen (*col. 6, 45-65*).

Response to Arguments

14. Applicant's arguments with respect to claims 1-37, 44, 46-63 and 74-89 have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jason Pinheiro whose telephone number is 571-270-1350. The examiner can normally be reached on M - F 8:00 AM - 4 PM;.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Robert Pezzuto can be reached on (571) 272-6996. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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01/29/2008